

URGENT FIELD SAFETY NOTICE

<p>Identification of the devices concerned</p>	<p>D²RS, including VISIONARY DRF and DX-D800 models.</p>
<p>Issue Description</p>	<p>We have detected a potential risk that could lead to a collision between the table column and the ceiling structure. This hazard could generate a breakdown of the column.</p> <p>This incident is due to the appearance of two simultaneous problems: a command has been kept active and the table software encountered a malfunction which does not allow to take into account the clearance parameters of the room anymore.</p>
<p>Risks related to the issue</p>	<p>Possible risk to harm a patient, a user, or a third if the column breaks.</p>
<p>Actions to be implemented by the users concerned.</p>	<p>As a precautionary measure and before your usual maintenance team intervention, the user should look at the equipment during all of its movement. He has to immediately release the command if an abnormal movement is detected. If necessary, he should use the emergency switch to stop the system.</p> <p>If unexpected problems occur, the user should contact XXXX .</p>
<p>Corrective actions taken by STEPHANIX</p>	<p>STEPHANIX plans to update the table software to completely eliminate this potential risk and ensure the safety of patients, users and third parties.</p> <p>Your technical team will contact you in order to make an appointment to perform this corrective action.</p> <p>For your information, the competent authorities concerned have been informed of this corrective action.</p>
<p>Additional information</p>	<p>If you need more information or technical assistance, you can phone your usual contact.</p>

La Ricamarie,
Date:

**URGENT FIELD SAFETY NOTICE
ACKNOWLEDGMENT**

We kindly ask you to return by email or by fax this document within 10 days, in order to attest that you have received this information note to the competent authorities.

Thanks you for your cooperation:

Company name:

Address:

Manufacturer reference:

RC1706820

Product concerned and serial number:

I confirm that I have received and read the following safety information and communicated it to the people and or/organisations concerned.

Please specify if:

The device concerned was sold / transferred to another customer:

Please specify the address below:

- Nom :
- Address :
- Contact :

The device concerned was dismantled/destroyed.

- Date :
- By :

Nom et fonction :	
Date :	
Signature and stamp	

Please, return this document completed and signed to the following email:
quality@stephanix.com